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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,139	08/10/2001	Marianne Langston	GJE-136D1	6929

23557 7590 02/14/2003

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/14/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/928,139

Applicant(s)
Langston et al.

Examiner
Celia Chang

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1625



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 8, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. The finality of the previous office action is hereby withdrawn. The after final response filed by applicants in Paper No.9, dated Jan. 8, 2003 has been considered as a response to the rejection of the office action of paper no. 7, dated sept. 24, 2002.

2. The rejection of claims 1-8 over Shaflee in view of Barry or Miller, Shaflee in view of Barry or Miller further in view of Rometsch, over Shaflee in view of Barry or Miller further over Rometsch and Jacques supplemented with Harris are maintained for reason of record.

Applicants argument is based on racemization of the "two chiral" center. Please note that racemization involving two chiral center was disclosed by Miller see col. 2, R,S-HPCA.DAA etc. which are material with two chiral center which are racemized for additional S-enantiomer (see col. 1 line 65-66). Criticality in racemization into "four" enantiomers, thus, is not because of the "two" chiral centers but the conditions employed to ensure all four enantiomers are formed simultaneously. Just because the prior art such as Rometsch did not *name* all four enantiomers, does not mean the racemization using the same acid would not give all four enantiomers. Such can only be obviated by *factual* comparison.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification lacks sufficient description to the instant claims because it is noted that the first step of the instantly claimed process is to resolve *dl-threo*-methylphenidate by the procedure described in the example of PCT/GB97/00185 which is now made of record. Please note that incorporation by reference of essential material is limited to US patent only. Proper incorporation of such material to the specification must be made.

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In addition, the material made by the example of PCT/GB97/00185 is the ditoluoyl-D-tartrate salt of *l-threo*-methylphenidate and ditoluoyl-D-tartrate salt of *d-threo*-methylphenidate. No descriptive support can be found as to how such salt is racemized (see p.2 scheme 1) nor was there any descriptive support as to how the two ditoluoyl-D-tartrate salt can be embraced by scheme 1 of the instant specification, or the claimed process.

Further, it is irrelevant arguments presented by applicants as to criticality of how many chiral center when "what" is being made, is it methylphenidate or methylphenidate ditoluoyl-D-tartrate; or "what" is being racemized, is it methylphenidate or methylphenidate ditoluoyl-D-tartrate; were not sufficiently disclosed in the specification.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman, can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7922.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

WP/Chang

Feb. 12, 2003



Celia Chang

Primary Examiner

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